REMARKS

Claims 28, 30-32, 34, 39 and 41 remain pending in the present application. Claim 39 is amended to address formal matters raised in the outstanding Office Action. No new matter is added.

Entry of the accompanying amendment under 37 C.F.R. 1.116 is requested since the amendment merely addresses formal matters and does not present new issues. In the alternative, entry is requested in order to place the claims into better form for consideration on appeal.

Rejection under 35 U.S.C. §112, second paragraph

Claim 39 is rejected under 35 U.S.C. §112, second paragraph as being indefinite. Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof in view of the accompanying amendment.

Rejections over Mori et al.

Claims 28, 30-32 and 39 are rejected under 35 U.S.C. §102(b) as anticipated by Mori et al. (U.S. 6,239,177). Claims 28 and 30 are rejected under 35 U.S.C. 103(a) as obvious over Mori et al. Claims 28 and 41 are rejected under 35 U.S.C. 103(a) as obvious over Mori et al. in view of Isaji et al. ("Tranilast: a New Application in the Cardiovascular Field as An Antiproliferative Drug", Cardiovascular Drug Reviews, Vol. 16, No. 3, pp. 288-299) in view of Pope et al. (US 5,498,822).

All outstanding prior art rejections are ultimately based upon the reference to Mori et al. (U.S. 6,239,177), which is defective as applied to all claims, as

discussed below. Accordingly, Applicants respectfully request reconsideration and withdrawal of all prior art rejections.

Initially, Applicants note that the Mori et al. reference has been cited and withdrawn by the Examiner previously during the course of prosecution. On June 24, 2009 the Examiner cited Mori et al. as the base reference in a number of rejections. Applicants responded on September 22, 2009, by amending claim 28 to replace the transitional phrase "comprising" with "consisting of", and with arguments that Mori et al., in all cases, necessitates inclusion of water in their compositions, which should be considered to be excluded by the amended claim language. At that point in prosecution, Applicants argued in pertinent part:

> The presently claimed composition is limited to having only Tranilast, a biodegradable polymer in the form of a film, foam, fibers and filaments and optionally a therapeutic agent. The delivery vehicle has (i) no solubilizer for Tranilast, (iv) no adhesive, and (v) *no water to form an aqueous base*, as required by Mori et al. (Response, page 6; underlining in original; italics added).

In an effort to expedite prosecution, Applicants' representative conducted a personal interview with the Examiner on October 6, 2009, at which time the Examiner agreed with Applicants' position with respect to Mori et al. In the interview summary issued after the interview, the Examiner stated:

> The current amended claims requiring the foam, fiber or filament to consist of tranilast or its analog and a biodegradable polymer and optionally another therapeutic agent overcomes the prior art of record in that the prior art of record contains other than tranilast and biodegradable polymer. The attorney and the examiner discussed making the fiber, the filament or the foam or film the subject of the claim. If the provisional obviousness-type double patenting rejection is the only rejection remaining after further search and consideration turns up no art, the provisional obviousness-type rejection will be dropped (so long as the co-pending is in pending status). (Page 2, emphasis added).

Now, after extended prosecution, including the filing of an Appeal Brief (August 9, 2010) and reopening of prosecution by the Examiner (December 22, 2010), the Examiner returns to Mori et al. as the sole base reference, having already agreed to dismiss same.

In the outstanding Office Action, the Examiner states:

> 13. Applicant's arguments on pages 7-10 centers on applicant's contention that Mori's composition contains water, which is excluded by the consisting language and that the examiner's argument that the patch of Mori does not contain water is not found in Mori.
>
> 14. Response: The examiner disagrees that Mori does not teach the claimed composition as follows:
>
> A) The rejection under 35 USC 102(b) is a new rejection in the office action of 12/22/2010. The final rejection of 01/08/2010 does not have this rejection and the Appeal Brief filed 08/09/2010 did not present arguments against the rejection under 35 USC 102(b). It is therefore unclear how the examiner may have responded to applicant's argument that [water] was not present. (Emphasis added).

In fact, the Mori et al. water content was precisely the point of Applicants' arguments during the personal interview, as well as those presented prior to the personal interview in their response of September 22, 2009. Contrary to the highlighted portion of the quotation above, the Examiner's position with respect to the arguments over Mori et al. was made clear in her comments set forth in the Interview Summary statement of October 6, 2009.

For the Examiner to suggest that this issue has not even been raised, let alone resolved, is at best disingenuous. The Examiner's statement in the Interview Summary made clear that any rejection over Mori et al. was overcome by the amendment of the transitional phrase to "consisting of".

Now, the Examiner reverts to Mori et al. as the base reference, contradicting her earlier agreement with Applicants that the present claim language excludes water.

> B) However, the presence of water in Mori meets the limitation of optional therapeutic agent and the presence of optional therapeutic agent does not exclude water. In fact water meets the limitation of optional therapeutic agent. Therefore, because claim 28 contains optional additional therapeutic agent, a composition containing water and/or other therapeutic agents meets that limitation. This is supported by the fact that the instant specification at paragraph [0037] of the published application mentions additional therapeutic agent without defining or disclosing agents that would be additional therapeutic agents.

Initially, Applicants request that the Examiner go "on-record" as to the therapeutic effects of water. Webster's Online Dictionary (http://www.websters-online-dictionary.org/definitions/therapeutic) defines "therapeutic" as:

> 1. Tending to cure or restore to health; "a therapeutic agent"; "therapeutic diets".

Applicants are unaware of any malady for which water is curative, and as such submit that contrary to the Examiner's interpretation of the term "therapeutic agent", water is not included.

Further, at the point in the specification cited by the Examiner for the proposition that the specification does not define or disclose agents that would be additional therapeutic agents, Applicants state:

> [0037] In another preferred embodiment of the present invention, a delivery vehicle in the form of a barrier and Tranilast could show greater efficacy if combined with other drugs at the time of surgery or pre-operatively. For example, an anti-fibrotic such as the recombinant plasminogen activator compound available under the tradename RETAVASE (Boehringer Mannheim Corp., Indianapolis, Ind.) would be delivered to the site at the time of surgery and then a barrier/collagen synthesis inhibitor (such as Tranilast) would be placed onto the site. The combined effect of the plaminogen activator compound limiting the

> clotting at the surgical site, the barrier limiting the apposition of the tissue surfaces and the Tranilast inhibiting collagen synthesis could dramatically reduce adhesions. The additional therapeutic agents also could be given systemically, by a variety of means, prior to, during or after surgery in conjunction with local, non-systemic administration post-operatively. In addition, as surprisingly discovered and described below, Tranilast may be administered systemically in conjunction with local, non-systemic administration of Tranilast. (Emphasis added).

Conveniently ignored by the Examiner is Applicants' further disclosure at paragraph [0038], wherein Applicants provide a list of other therapeutic agents which can find use in the presently claimed invention:

> [0038] Therapeutic agents that may be used in combination with Tranilast may fall in the general classes of anti-platelet, anti-fibrotic, anti-inflammatory, anti-proliferative, and/or inhibit collagen synthesis. These include, but are not limited to, Urokinase, the nonglycosylated deletion mutein of tissue plasminogen activator available under the tradename RETAVASE (Boehringer Manheim, Indianapolis, Ind.), pharmaceutical preparations containing abciximab for the prevention and treatment of diseases of the circulatory system available under the tradename REOPRO (Eli Lilly and Company, Indianapolis Ind.), Clopidogrel Bisulfate, available under the tradename PLAVIX (Sanofi-Synthelabo, Paris, France), pharmaceutical preparations containing imatinib mesylate for use in the field of oncology available under the tradename GLEEVEC (Novartis AG, Basel Switzerland), Triamcinolone Acetonide, Tepoxalin, Pirfenidone, collagenase, anti-CTGF, tyrosine kinase inhibitors, prolyl hydroxylase inhibitors, lysly oxidase inhibitors, C-proteinase inhibitors, N-proteinase inhibitors, TGF.beta. inhibitors such as Tamoxifen, HMG-CoA Reductase inhibitors such as Lovastatin, COX-1 and/or COX-2 inhibitors such as Ibuprofen, Nimesulide, pharmaceutical preparation containing vofecoxib for the treatment of arthritis available under the tradename VIOXX (Merck & Co., Inc. Whitehouse Station N.J.), pharmaceuticals in the nature of anti-inflammatory analgesics containing celecoxib available under the tradename CELEBREX (G.D. Searle & Co., Skokie Ill.), pharmaceutical preparations containing valdecoxib available under the tradename BEXTRA (Pharmacia & Upjohn Co., North Peapackn N.J.), Calcium ion inhibitors such as Amlodipine, Nifedipine, pharmaceuticals such as verapamil used in the treatment of hypertension, iron chelators such as deferoxamine available under the tradename DESFERAL (Novartis AG, Basel Switzerland), antibiotics such as Clarithromycin and Ciprofloxin retinoids such as Tretinoin and Retinoic Acid, chymase inhibitors, 9-methyl-3-(1H-tetrazol-5-yl)-4H-pyrido[1,2-.alpha.]pyrimidin-4-one potassium, known as Pemirolast, and analogs thereof. When used in combination with Tranilast, the therapeutic agents, or drugs, are present

> in an amount effective to provide the therapeutic effect intended by administration of the therapeutic agent. (Emphasis added).

Notably, water does not appear in the list.

Accordingly, Applicants submit that the Examiner's interpretation of the claim term "additional therapeutic agent" as including water is without merit, and is unreasonable when read in light of the specification.

> "Claims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification in giving them their 'broadest reasonable interpretation'." *In re Marosi*, 710 F.2d 799, 802 (Fed. Cir. 1983), (quoting *In re Okuzawa*, 537 F.2d 545, 548, 190 USPQ 464, 466 (CCPA 1976)) (emphasis in original). The court looked to the specification to construe "essentially free of alkali metal" as including unavoidable levels of impurities but no more.). Compare *In re Weiss*, 989 F.2d 1202, 26 USPQ2d 1885 (Fed. Cir. 1993) (unpublished decision - cannot be cited as precedent) (The claim related to an athletic shoe with cleats that "break away at a preselected level of force" and thus prevent injury to the wearer. The examiner rejected the claims over prior art teaching athletic shoes with cleats not intended to break off and rationalized that the cleats would break away given a high enough force. The court reversed the rejection stating that when interpreting a claim term which is ambiguous, such as "a preselected level of force", we must look to the specification for the meaning ascribed to that term by the inventor." (Emphasis added). The specification had defined "preselected level of force" as that level of force at which the breaking away will prevent injury to the wearer during athletic exertion.) **MPEP 2111.01 (II)**.

Withdrawal of all rejections based on Mori et al. is requested.

Rejections for Provisional Nonstatutory Double Patenting

Claims 28, 30-32 and 39-41 are provisionally rejected for nonstatutory double patenting over claims 14, 19, 21-23, 27, 28, 31, 34, 37 and 39-41 of copending application no. 10/780,452, in view of Chandrasekar et al. ("Platelets and Restenosis") or Miyazawa et al. ("Effects of pemirolast and tranilast on intimal thickening after arterial injury in the rat").

Claims 28, 30-32 and 39-41 are provisionally rejected for nonstatutory double patenting over claims 1-6, 11, 14-16, 19, 21-25, 27-34, 37, 40 and 41 of copending application no. 12/021,546, in view of Chandrasekar et al. ("Platelets and Restenosis") or Miyazawa et al. ("Effects of pemirolast and tranilast on intimal thickening after arterial injury in the rat").

Applicants request that the requirement to respond to the double patenting rejections be held in abeyance until notification of allowable subject matter in the present application, at which time Applicants will consider submitting a Terminal Disclaimer over one or both of the cited copending applications.

In view of the foregoing, it is respectfully submitted that the present claims are in condition for allowance. Prompt notification of allowance is respectfully requested.

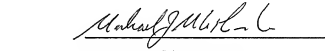
The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 50-2478(15314).

If the Examiner has any questions or wishes to discuss this application,

the Examiner is invited to contact the undersigned representative at the number set forth below.

Respectfully submitted,

Date: October 11, 2011



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